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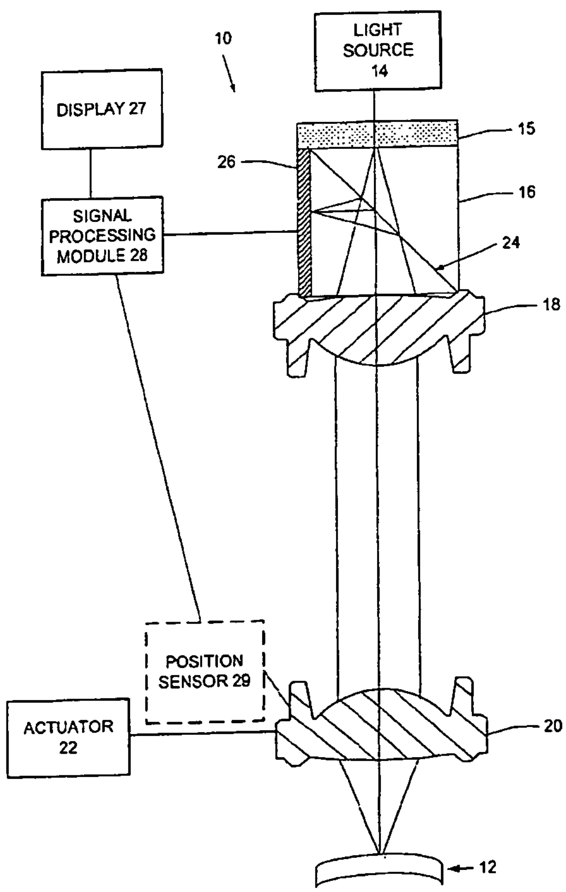
(54) Title: CORNEA CHARACTERISTICS MEASURING DEVICE



(57) **Abstract:** An apparatus (10, 50) for measuring characteristics of a substance (12) is provided. The apparatus (10, 50) includes a light source (14, 52, 54, 56) to generate light to form an image. A splitter (16, 58, 60, 62) transmits the light from the light source to a first lens (18), which collimates the light. A second lens (20) receives the collimated light and is adapted to oscillate with respect to the substance (12) and adapted to transmit and focus the light to a focal region within the substance (12), such that the oscillation will cause the focal region to pass back and forth through the substance (12). A sensor (26, 64, 66, 68) receives light reflected from the focal region and provides a signal indicative of characteristics of the substance (12) at the focal region.

WO 2004/034894 A1

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CORNEA CHARACTERISTICS MEASURING DEVICE

BACKGROUND OF THE INVENTION

Measurements of characteristics of the eye are useful in providing appropriate eye care. For example, measurements of the eye have been useful in refractive surgical procedures, such as LASIK, wherein a portion of eye tissue is removed to enhance vision of a patient. Additionally, measurements are useful in studying the eye and diagnosing eye disorders.

In refractive surgical procedures, the thickness of the cornea is a valuable parameter in determining how much tissue of the eye should be removed. The thickness of the cornea is also valuable in diagnosis, prognosis, medical & surgical procedures, and monitoring of other conditions, such as glaucoma. Devices known as pachymeters (or alternatively pachometers) are used to measure the thickness of the cornea.

Corneal haze is another characteristic measured and used in the treatment and study of eyes. Corneal haze results from an alteration of corneal transparency, which may negatively impact vision. Many eye disorders such as macular corneal dystrophy, bullous keratopathy, keratoconus, lumican deficiency (in mice), fungal infection and endothelial injury are thought to contribute to corneal haze. Additionally, haze may form after surgical procedures or injuries.

One device that measures characteristics of the eye is an ultrasonic probe. Ultrasonic probes use sound

waves to obtain measurement data, typically a measurement of the thickness of a cornea at a particular point. The probes generally contact the cornea during measurement, causing discomfort to the patient. Further, the measurement process using an ultrasonic probe may require several minutes if multiple measurements are necessary to achieve accurate results. The accuracy of ultrasonic pachymetry is also dependent upon accurate knowledge of the speed of sound in corneal tissue, which may range from 1200 to 2000 meters per second in different eyes. Finally, it is difficult to assure perpendicularity of the measurement axis to the corneal surface. Lack of perpendicularity may result in erroneously large measurements.

Another device that measures characteristics of the eye is a corneal confocal microscope. A confocal microscope illuminates a small region of a substance, such as a cornea, with a collimated light source focused through an objective lens to a tiny volume of space at the focal region of the lens. A detector that is "confocal" with the focal volume detects any backscattered or reflected light from the focal region. A viewable histological image is formed by a confocal microscope. One disadvantage of confocal microscopes is that they are extremely expensive and complex. Thus, confocal microscopes are not readily available to provide measurements of an eye. In addition, confocal microscopes are big, bulky devices that may be difficult to maintain, align, and transport. The

confocal microscopes also cause patient discomfort due to the fact that the lens of the microscope contacts the cornea and the light source of the microscope is bright. The measurement time can last several minutes.

In a corneal confocal microscope, signals detected by the detector form images that may be analyzed to measure the thickness or opacity of the cornea and may further be used to generate a topographical or tomographical image of the cornea. Images taken of a cornea using a confocal microscope can also provide a visual representation of corneal haze.

As one might imagine, a system of quantification of corneal haze is useful in diagnosis and in assessment of various experimental treatments or prevention protocols. Many such methods for haze quantification have been developed. Clinically, haze is evaluated by "slitlamp" examination, ranked on a scale from 0 to 4 with 0 being normal and 4 being quite severe. However, this scale is subjective and only coarsely defines the amount of corneal haze.

As a result, it is desirable to have a low cost device that can measure various characteristics of the eye, such as thickness and haze. Furthermore, a standardization of corneal haze is desirable to further aid in experimentation, reporting, and analysis of corneal haze.

SUMMARY OF THE INVENTION

An apparatus for measuring characteristics of a substance is provided. The apparatus includes a light

source to generate light and a collimating lens to collimate the light. In one embodiment, a pattern of multiple measurement points are formed from the light. A filter such as a hologram or grating can be used to form an image of several points from the light via interference effects. An arrangement of pinholes can also be used to create a source image of multiple points for simultaneous measurement of multiple focal regions.

A fixed lens collimates light from the filter. An objective lens receives the collimated light and is adapted to focus light in an oscillatory manner. In one embodiment, the objective lens is adapted to oscillate with respect to the substance under analysis and to transmit and focus the light into the substance (or to the highly reflective surfaces and interfaces of the substance as scanning of the focal region proceeds). A portion of the light reflected from the focal region or regions in the substance is then effectively re-collimated by the objective lens and directed along the original path, in the reverse direction, then partially deflected (through use of a beam splitter or fiber-optic couplers). This reflected light provides a signal indicative of characteristics of the substance at the focal region (or focal regions, if a hologram and multi-sensor array are used to simultaneously analyze multiple points). The portion of the light reflected from points other than the focal region is rejected

through use of an appropriate spatial filter, according to the confocal principle.

Also, as another aspect of the present invention, a method is provided for quantitatively measuring characteristics of a cornea. The method includes generating light and collimating the light with a first lens. The light from the first lens is focused into a focal region of the cornea with a second lens. A portion of light reflected from the focal region is sensed and a signal indicative of the portion of light reflected is provided.

To quantify corneal haze, a series of standard reference solutions having known turbidity values are measured with the device, with the known turbidity of each corresponding to the measured signal strength. Next, or in the alternative before the foregoing, a measurement of the turbidity of the cornea is taken using the same device under the same operational parameters in a timeframe in which the operational characteristics of the instrument may be assumed to be constant. After all measurements are taken, the measurements are analyzed and compared, and the turbidity of the cornea is assigned a value according to the appropriate interpolation of its signal strength compared to the standard turbidity scale from the standard solution measurements.

In yet another aspect of the present invention, a kit of secondary standards appropriate for the given device are provided so that correct

instrumental calibration may be verified more conveniently in a setting less amenable to the primary standard, such as a clinic. The secondary standard kit samples may also serve as standards for characteristics other than haze, such as thickness. For example, plates may be of a certain thickness and/or opacity to provide simultaneous calibration for measurement of both properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic view of a device according to the present invention.

FIG. 2 is a schematic view of an actuator according to the present invention.

FIG. 3 is a plot of various measurements taken of a cornea.

FIG. 4 is a schematic view of an alternative embodiment of the present invention.

FIG. 5 is a diagram of a plurality of measurements taken of a cornea.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A device 10 as schematically illustrated in FIG. 1 can be assembled in order to provide a signal indicative of the thickness and/or opacity of a sample 12. Device 10 includes a light source 14 (herein a visible diode laser, but the light, which is defined herein broadly as electromagnetic radiation, could be visible and/or non-visible, coherent and/or non-coherent) that passes light first through a filter 15, such as a pinhole, hologram or

other suitable means of image generation as necessary, to create an image (for example, three points arranged as the vertices of an equilateral triangle). Any type of image or number of focal spots can be used as discussed below. The light produced by light source 14 may be emitted from diode lasers, visible and/or white light emitting diodes or infrared emitting diodes, or traditional light bulbs, for example.

The light then passes through a splitter 16 that deflects a portion of the light. Splitter 16 illustratively may be a beam splitter cube, fiber optic coupler, or other component. Light that has passed un-deflected through splitter 16 then passes through a lens 18, which collimates the light and transmits it to scanning lens 20. Lens 20 may be the final objective lens, or merely the scanning element before a final objective lens. Actuator 22 is provided to actuate lens 20 such that a high number of measurements taken along the axis of motion may be obtained in a short time period and to focus light through the sample 12. In one embodiment, lens 20 is actuated in a direction toward (and away) from sample 12 along the axis of the collimated light beam.

It is worth noting that a stationary objective lens can also be used. In order to scan through the cornea, an objective lens with a high chromatic aberration characteristic should be used and the light source should provide light with varying

frequencies that are refracted to different focal points in the sample. Additionally, a multi-element detector adapted to detect the light at different frequencies should be used. In an alternative embodiment, a grating-prism combination (known as GRISM) can be used to scan through the cornea.

Light that reflects from a focal region within sample 12 is reflected back to reflector 24 within splitter 16. Reflector 24 then reflects light onto sensor 26 to sense parameters of the reflected light. For example, sensor 26 can include an appropriately small active element or any detector or detector array with proper spatial filtering for the original light configuration from light source 14. Sensor 26 provides a signal (or signals) indicative of thickness and/or opacity of sample 12 to signal processing module 28. Signal processing module 28 calculates the thickness and/or opacity of sample 12 given the signals received from sensor 26. A display 27 or other rendering device can be coupled to the signal processing module 28 and is adapted to display an output of the calculation from signal processing module 28.

In one embodiment, the lens 18 and/or 20 is a plastic aspheric lens similar to those originally designed as a collimation and objective lens for diode laser sensing applications, particularly CD-ROM heads and laser pointers. A wide selection of low-cost plastic lenses are available. These lenses are

helpful for two reasons. First, the low mass of the plastic lens enables high-frequency scanning, in the range of tens to hundreds of Hertz. This feature can be important in a hand-held device, since the measurements can be taken on a time scale where little relative movement occurs between the operator's hand, the instrument, and the cornea. Second, these optimized aspheric lenses have the high numerical apertures that provide successful confocal optical sectioning.

The axial resolution of confocal optics is largely governed by a characteristic of the lens known as the numerical aperture (NA). Any size NA may be used, although axial resolution may be compromised. With well-engineered detector circuitry, a lower NA lens may be used. A high NA lens provides increased resolution, although one drawback of high NA lenses is the shorter working distance (WD). In one embodiment, a device with an approximately 3 mm working distance can be achieved with a .47 NA lens, while an approximately 8.3 mm WD can be met with a .22 NA lens. This working distance is an improvement compared to contact ultrasound instruments, as well as current confocal instruments, which require much more complex objective lens assemblies to achieve their primary function, histologic imaging.

A suitable feedback mechanism can be employed in order to notify an operator of the device that the

device is in a suitable range of operation corresponding to the working distance. For example, the feedback can be audio or visual based on the signals detected by sensor 26. Signal processing module 28 can provide appropriate feedback to the operator when reliable signals are received from sensor 26. If the object to be measured is outside the working distance of the device, unreliable or weak signals will be received by sensor 26.

In another embodiment of the present invention the objective tip of the instrument could be integrated into an applanation instrument for simultaneous or nearly simultaneous measurement of corneal thickness and intra-ocular pressure by a form of tonometry. Providing pressure and thickness measurements in the same instrument would save time and also aid in developing a correlation between pressure and thickness, particularly with regard to diseases such as glaucoma.

Actuator 22 can be a mechanical oscillator driven by an electronic circuit. In one embodiment, as illustrated in FIG. 2, the actuator 22 includes a drive circuit 30 that provides a signal to scan lens 20 at a rate of more than 100 Hz via electromagnetic force interaction. The speed of mechanical oscillation is governed by mechanical and physical characteristics of the scanning mechanism. Higher speeds are, in general, desirable, if the data acquisition system can support rapid detection.

Drive circuit 30 includes an oscillator control, for example a 555 timer, and an output transistor to drive a coil 35. Alternatively, the oscillator control might provide an initial kicking impulse to the coil, and then rely on an electromagnetic triggering scheme incorporated into an armature coupled to the lens 20, to provide reliable, self-calibrated harmonic resonant oscillation. This scanning allows the device 10 to yield many data points in a short period of time (measured in seconds or fractions of a second). As lens 20 moves axially with respect to the collimated light, the focal point of the lens 20 moves throughout the sample 12.

As previously stated, the device is able to scan the objective lens 20 along the axial dimension at a frequency of tens to hundreds of Hz, over a distance of millimeters. This scanning is easily accomplished by mounting the lens 20 on an armature 32 such as a piece of spring-steel or similar material, and then "kicking" the oscillator at its natural frequency through use of an electromagnetic coil 35 driven by drive circuit 30 and an attached permanent magnet 36. Instead of a single armature, a design with multiple parallel armatures could be used to increase the linearity of the scanning translation motion. Alternatively, other spring types may be used, such as coil springs or bellows springs. Different spring geometry may be advantageous to alter scanning speed, device geometry, or the ease with which the device

may be manufactured, assembled, and aligned. While other arrangements, such as a voice coil motor, a rotational motor and camshaft mechanism, or a piezoelectric actuator are possible, the spring scanning arrangement is simple and stable, similar to a tuning fork. It is simple and inexpensive to build the circuits to accomplish the scanning, as the components are largely similar to simple components found in audio circuits or electro-mechanical clocks. Audio signals have been used to find the resonance frequency of a particular arrangement, and simple square-wave oscillators have also been used. These circuits are based on a 555 timer IC and a small output transistor that controls current flow through the voice coil, but more sophisticated forms of pulse code modulation are possible. An electromagnetically-driven scanner has the advantage of cost, tunability, simplicity, reliability, speed, and low power consumption necessary for a hand-held device.

The physical position of the scanning armature 32 may either be monitored and recorded as a separate data track (via optical, magnetic, capacitive, Hall effect sensor, or any other means), or simply be a well-characterized motion achieved through precision manufacture and verified through measurement of an object of known thickness. A suitable position sensor 29 may be provided to measure the position of lens 20 and provide an output indicative of a position of

lens 20 to signal processing module 28. When device 10 scans through the sample 12, in particular a cornea, regions corresponding to front and back surfaces are bright and reflective. Images received by sensor 26 correspond to different brightness values.

When the value or values are plotted as a function of focal depth, a characteristic curve as illustrated in FIG. 3 results. The curve can be representative of a single scan or multiple scans that are averaged. In FIG. 3, both the epithelium (the outermost layer of cells of the cornea) and endothelium (the innermost layer of the cornea) produce relatively large peaks, illustrated as peaks 40 and 42, respectively. A distance 44 between peaks 40 and 42 provides an accurate measurement of corneal thickness when the movement and optical characteristics of the scanning mechanism that generated the signal are known. In one embodiment, signal processing module 28 is a computer that includes an algorithm to compute the height and position of the peaks. The signal processing module 28 may provide results on display 27. As appreciated by those skilled in the art, analog circuitry or combinations of analog and digital circuitry can be used for signal processing and pre-processing. Furthermore, signal processing module 28 may be embodied in a conventional computing environment that

collects, stores and analyzes signals received from sensor 26.

If desired, an arrangement of three or more fiber optic tips may be used as light source 14, which creates three or more signals. A similar image may be achieved with a hologram or a pinhole array. For example, a light delivery system with a fiber optic tip serves as both the light source 14 and the sensor 26. The fiber optic tip as light source 14 and sensor 26 provides a rugged, self-aligned design, and the beam splitter may also be replaced by a fused fiber coupler in this embodiment. In one embodiment, a multimode fiber having a 62 micron core is used. Another embodiment uses a single mode fiber having an 8 micron core.

FIG. 4 illustrates a schematic view of a device 50 using a fiber optic coupler 51 as the light source and detector. In one embodiment, a fused fiber optic coupler can self-align the light source and detector in a single component to assure that the light source and detector are confocal. A rugged, single component additionally prevents disruption of the alignment during operation. Components in FIG. 1 are similarly numbered in FIG. 4. In the embodiment illustrated, three fiber-coupled laser diodes 52, 54, 56 emit light to three 2X1 fiber splitters 58, 60 and 62, respectively. Undeflected light from splitters 58, 60 and 62 is passed through fibers (which serve as pinholes) to fixed lens 18. Light from the splitters

are focused on three spots (that can form apices of an equilateral triangle) within sample 12, while lens 20 focuses the focal spots through sample 12. Light reflected from sample 12 is detected by three fiber-coupled photo detectors 64, 66 and 68 coupled to splitters 58, 60 and 62, respectively. The photo detectors 64, 66 and 68 provide signals to signal processing module 28. A relative phase error between return signals sensed by the detectors can be used to determine the angle at which device 50 is held. Calculations can then be made by signal processing module 28 to correct for the angle at which the device 50 is held.

Three-dimensional multiple point measurement (3d Triangulation) is an advantage over ultrasound technology. Instead of simply using one focal spot, three or more focal spots can be synchronously focused in an oscillatory manner through the cornea. Three plots (70, 72 and 74) are shown in FIG. 5, as might be generated by oscillating the three focal spots through sample 12 at a skewed angle relative to the surface normal vector. The optics are such that the spots form the apices of an equilateral triangle in three dimensional space, thereby defining a plane. If the axis of the objective scanning is normal (perpendicular) to the plane of the cornea, the three signals will be in phase. If, however, the probe is not in perfect alignment (as one might expect in a hand-held device), a simple trigonometric equation

allows the device to calculate the angle at which the probe is held using the phase error of the three signals (appropriately mapped back to Cartesian space according to their motion characteristics) and the known spacing of the focal points in three dimensional space, which then further allows the proper corneal thickness to be calculated.

Ultrasound probes suffer from the fact that misalignment during measurement can yield widely varying results. In order to create the "three spot pattern" or some similar illumination geometry, one may employ either common gratings or a computed or traditionally generated holographic mask. Such technology is inexpensive, and would result in clean patterns while minimizing the "wasted light" from the light source. Computed holographic masks could easily form greater than 1/2 the beam energy into three perfectly spaced spots, or some other suitable geometry. If a "custom mask" is prohibitively expensive, two perpendicular gratings may be used to create a 3X3 grid pattern, and similar results achieved with a modified algorithm. Finally, a hologram laser, which is an integrated optical device used in optical data readers consisting of a diode laser, hologram image formation component, beam splitter, and light sensor, could be used to consolidate various separate components of the device and reduce the size of the device and reduce the cost

associated with alignment difficulty of the various components.

It will further be appreciated that the intensity of signals received from a sample 12 can be interpreted as a measurement of turbidity of the sample, which can be compared to a measurement of a standard material to quantify an amount of haze present in a cornea. Healthy corneas are quite transparent and only scatter approximately 2% to 10% of incident light across the visible spectrum. Corneal haze is thought to be the result of incongruities in the cornea, which causes an increase in the amount of scattered light in the cornea. Referring to FIG. 3, the relative intensity of data points between peak 40 and 42 may be extracted in order to provide a relative measurement of the turbidity of sample 12. The relative measurement can be compared to a substance having a known turbidity. As a result of the comparison, a quantified measurement of haze in sample 12 results. Accordingly, an objective quantified value of haze can be determined.

A standardized substance may be used having a known turbidity to calibrate devices 10 and 50. For example, a set of calibrating plates having known turbidity values can be used to perform the calibration. After calibration has been performed, signal processing module 28 can interpret signals received from devices 10 and 50 in order to provide a

relative output using values obtained from the calibration plate. Calibration of thickness measurement may also be achieved by using a substance (such as a plate) having a known thickness. A kit including several reference plates of known parameters such as opacity and thickness is useful in providing an easy way to calibrate devices 10 and 50.

In one embodiment, a calibrated reference solution such as formazin polymer suspension of known concentration is measured with the instrument, and this measurement is then compared to measurements of the cornea to provide reproducible results of the amount of haze in a cornea. Varying amounts of formazin turbidity may be used as reference values to quantify corneal range. For example a range of 0-4000 Nephelometric Turbidity Units (NTU) for formazin may be used as a primary standard in the development of a secondary standard of haze measurements.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An apparatus for measuring characteristics of a substance, comprising:

a light source to generate light;

a first lens to collimate the light from the light source;

a second lens receiving the collimated light transmitted through the first lens and adapted to focus the light into a focal region in the substance; and

a sensor receiving the light reflected from the focal region in the substance and provide a signal indicative thereof.

2. The apparatus of claim 1 and further comprising a signal processing module receiving the signal from the sensor and providing an output indicative of properties of the substance at said focal region.

3. The apparatus of claim 2 and further comprising a display coupled to the signal processing module to display the output.

4. The apparatus of any of claims 2-3 wherein the signal processing module is adapted to provide a feedback signal indicative of an acceptable working distance from the apparatus to the substance.

5. The apparatus of any of claims 2-4 wherein the output is indicative of a thickness of the substance.

6. The apparatus of any of claims 2-4 wherein the output is indicative of an opacity of the substance.

7. The apparatus of any of claims 1-6 and further comprising a filter to form an image pattern of light from the light source.

8. The apparatus of claim 7 wherein the image pattern includes at least three focal spots, spaced apart from one another.

9. The apparatus of claim 8 wherein the sensor receives reflected light indicative of the at least three focal spots and wherein a signal processing module is coupled to the sensor and calculates a relative phase difference of signals associated with each of the at least three spots and provides an output indicative thereof.

10. The apparatus of any of claims 1-9 and further comprising a beam splitter to partially deflect light from the light source and reflect light from the focal region of the substance to the sensor.

11. The apparatus of any of claims 1-10 and further comprising an actuator operably coupled to the second lens to oscillate the second lens along the axis of the direction of the light.

12. The apparatus of any of claims 1-11 wherein the light source is a fiber optic coupler.

13. The apparatus of any of claims 1-11 wherein the light source is a light emitting diode.

14. The apparatus of any of claims 1-11 wherein the light source is a laser.

15. The apparatus of any of claims 1-14 and further comprising a position sensor operably coupled to the second lens to sense a position of the second lens.

16. A kit comprising the apparatus of any of claims 1-15 and at least one calibration plate having a known parameter to provide a reference for calibrating the apparatus.

17. The kit of claim 16 wherein the known parameter is a thickness of the plate.

18. The kit of claim 16 wherein the known parameter is an opacity of the plate.

19. An apparatus, comprising:

a light source to generate light;

means for focusing the light throughout a substance at a focal region; and

means for detecting light reflecting off of the substance that is confocal with the focal region.

20. The apparatus of claim 19 and further comprising means for calculating a thickness of the substance.

21. The apparatus of any of claims 19-20 and further comprising means for calculating an opacity of the substance.

22. The apparatus of any of claims 19-21 wherein the means for focusing includes a first lens

to collimate the light and a second lens adapted to actuate in a direction parallel to the light and focus the light into a focal region of the substance.

23. The apparatus of any of claims 19-22 and further comprising means for filtering the light to form an image pattern.

24. A method of quantitatively measuring characteristics of a cornea, comprising:

generating light;

collimating the light with a first lens;

focusing the light with a second lens into a focal region of the cornea;

sensing a portion of light reflected from the focal region of the cornea; and

providing a signal indicative of the portion of light reflected.

25. The method of claim 24 and further comprising displaying the signal indicative of the portion of light reflected.

26. The method of any of claims 24-25 wherein the signal is indicative of a thickness of the cornea.

27. The method of any of claims 24-26 and further comprising comparing the signal to a reference signal indicative of a known thickness.

28. The method of any of claims 24-27 wherein the signal is indicative of an opacity of the cornea.

29. The method of claim 28 and further comprising comparing the signal to a reference signal indicative of a known opacity.

30. The method of any of claims 24-29 and further comprising filtering the light to form an image pattern of light.

31. The method of claim 30 wherein the image pattern includes at least three focal spots, spaced apart from one another.

32. The method of claim 31 and further comprising receiving reflected light indicative of at least three focal spots and calculating a relative phase difference of signals associated with each of the at least three spots.

33. The method of any of claims 24-32 and further comprising partially deflecting light and reflecting light from the focal region with a beam splitter.

34. The method of any of claims 24-33 and further comprising partially deflecting light and reflecting light from the focal region with a fiber optic coupler.

35. The method of any of claims 24-34 and further comprising actuating the second lens along an axis of the direction of light to focus the light into the cornea.

36. The method of claim 35 and further comprising monitoring a position of the second lens.

37. The method of any of claims 24-36 and further comprising providing a feedback signal indicative of an acceptable working distance between the second lens and the cornea.

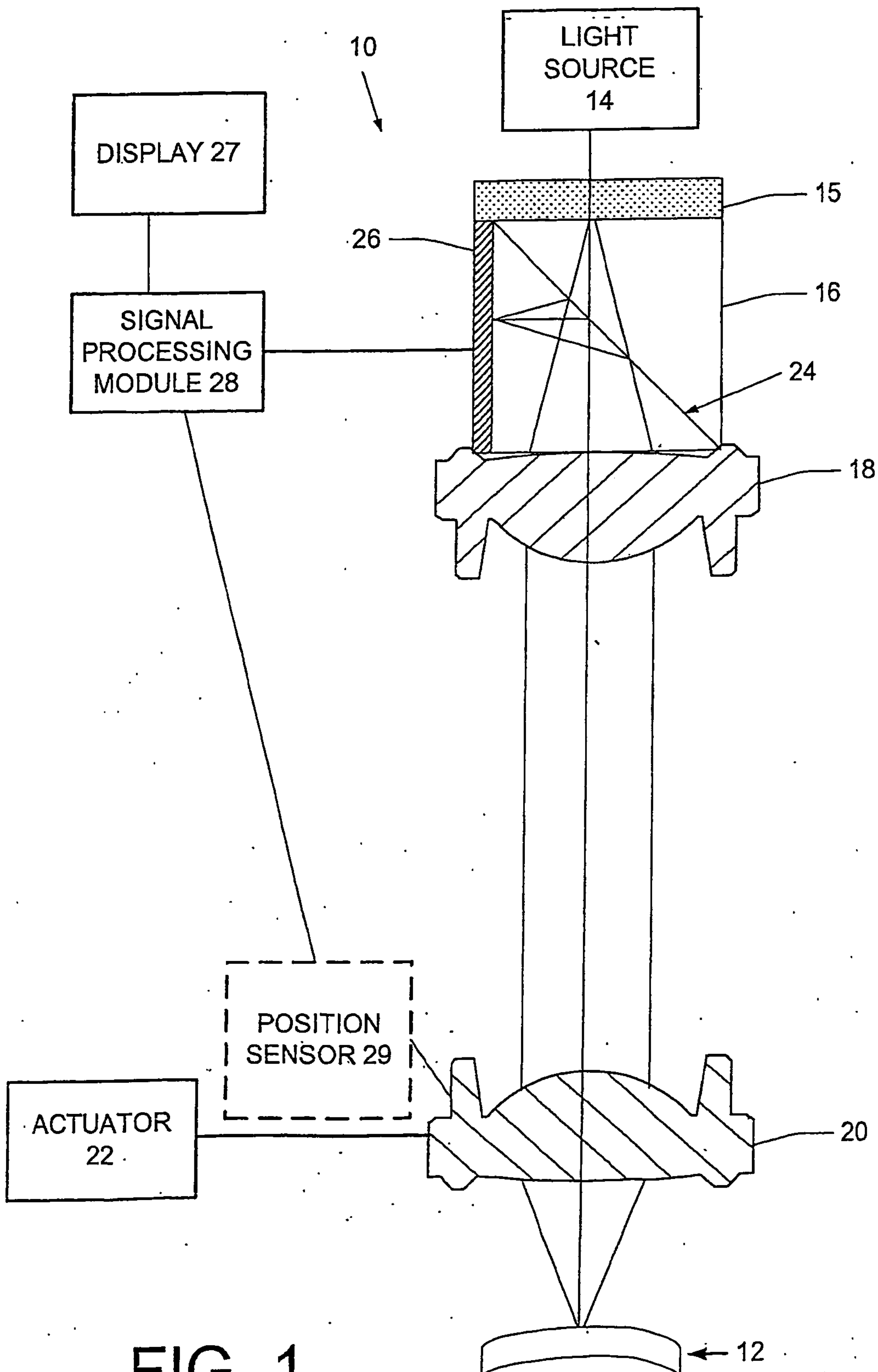
10
LIGHT SOURCE 14
DISPLAY 27
15
26
16
SIGNAL PROCESSING MODULE 28
24
18
POSITION SENSOR 29
ACTUATOR 22
20
12

FIG. 1

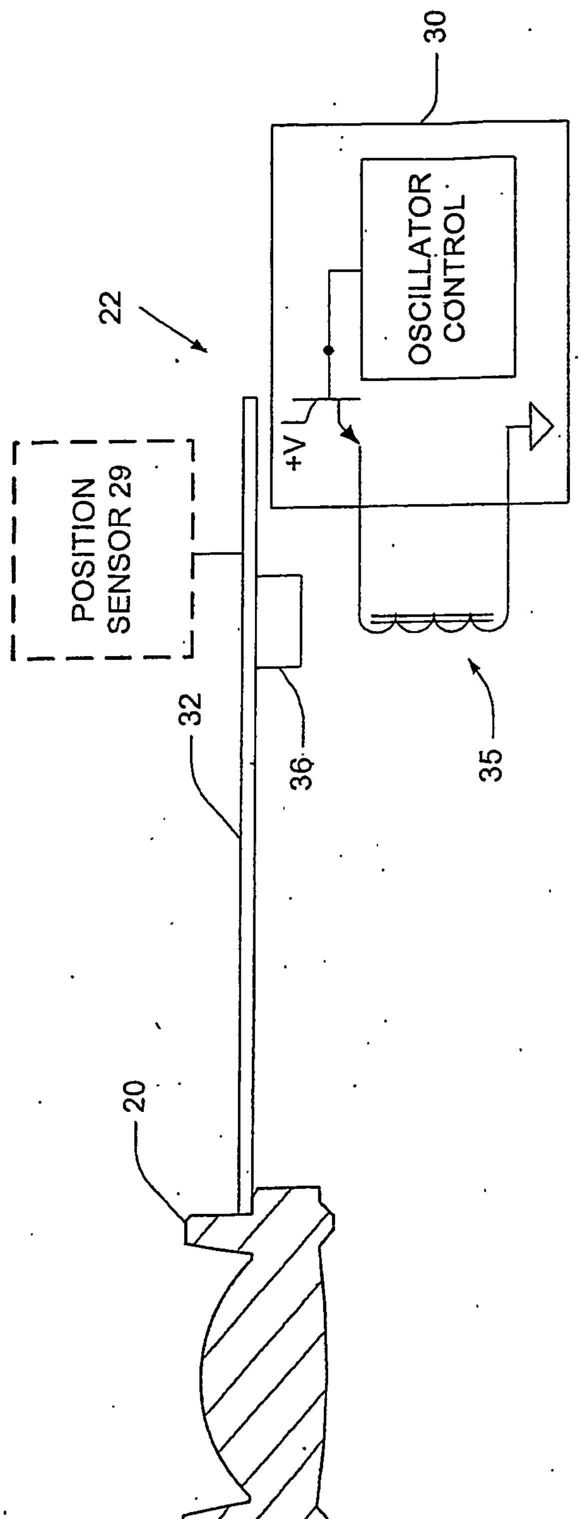

FIG. 2

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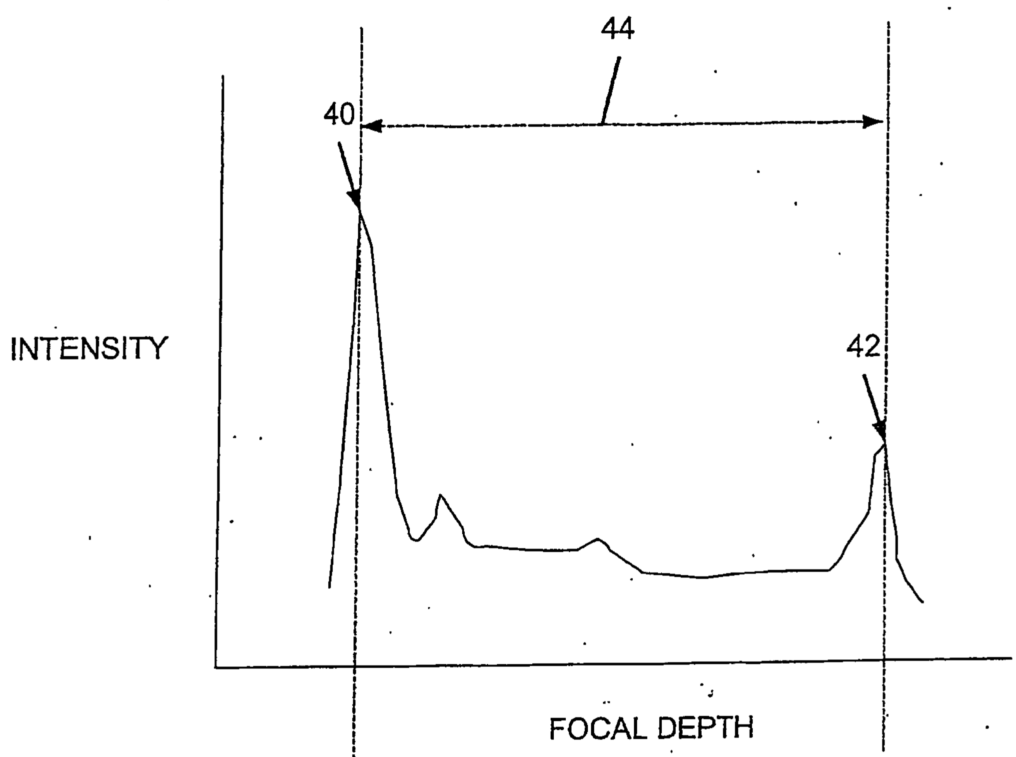

FIG. 3

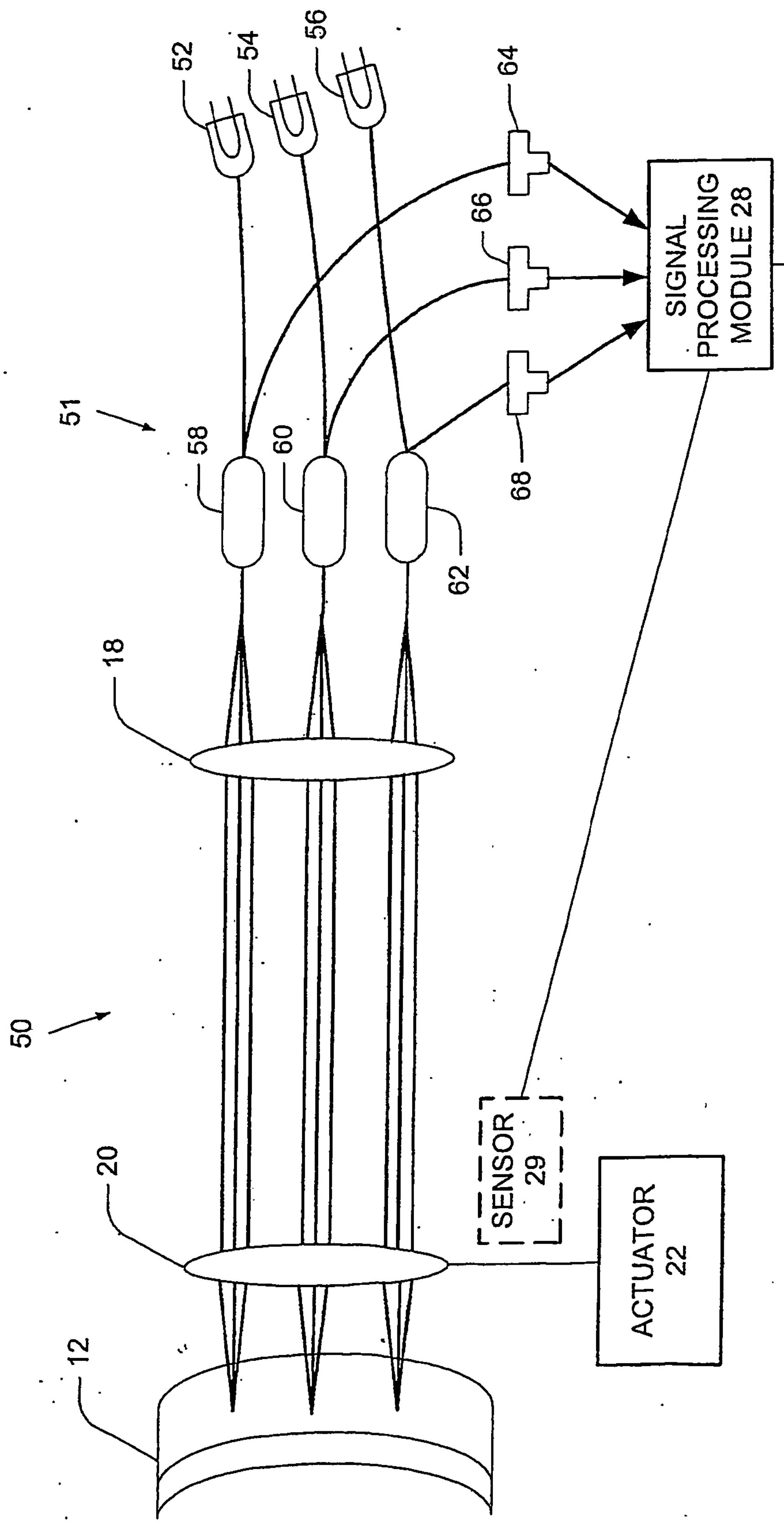

FIG. 4

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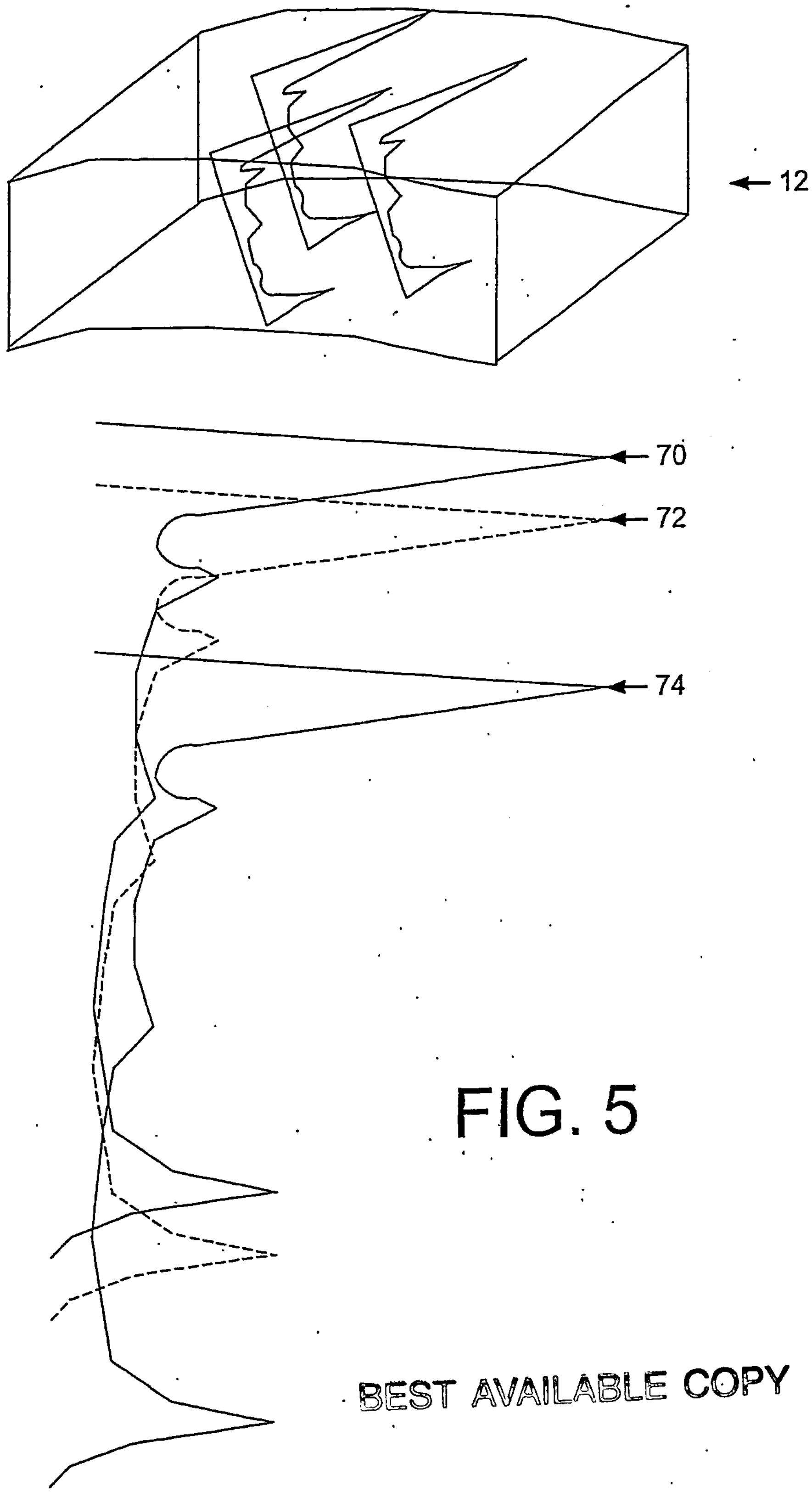

FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/32536

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B3/10 G02B21/00 G01B11/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G02B G01B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 810 457 A (KOVEX CORP) 3 December 1997 (1997-12-03) column 1, line 50 -column 2, line 47 column 3, line 30 - line 43 column 4, line 32 -column 5, line 52 column 8, line 3 -column 11, line 34; claims 1,5-7,10,11; figure 1 --- -/--	1-5,10, 11, 14-17, 19,20, 22, 24-27, 33,35-37

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
17 February 2004	25/02/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Rick, K

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International Application No
PCT/US 03/32536

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	DE 196 32 594 A (SCHWIDER JOHANNES PROF DR) 19 February 1998 (1998-02-19) column 1, line 30 -column 2, line 14; claim 1; figures 1,2	1-3, 7-10,14, 19, 22-25, 30-33
X	GB 2 144 537 A (OTTICA IST NAZ) 6 March 1985 (1985-03-06) page 1, line 118 -page 2, line 77; figures 1,2	1-3,7, 10,11, 19, 22-25, 30,33,35
X	US 4 806 004 A (WAYLAND J HAROLD) 21 February 1989 (1989-02-21) column 5, line 17 -column 8, line 17 column 11, line 25 - line 39; claim 1; figure 3	1-3,7,8, 10-14, 19, 22-25, 30,31, 33-35

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 015, no. 207 (P-1207), 28 May 1991 (1991-05-28) & JP 03 055510 A (SUMITOMO CEMENT CO LTD), 11 March 1991 (1991-03-11) abstract ---	7-10, 30-34
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